

discovery that loss or reduction of ABH1 function leads to enhanced sensitivity to ABA in plants, which renders the plants drought resistance.

## **II. Status of the Claims**

Claims 28-43 have been canceled. New claims 44-61 have been added.

The new claims find support throughout the specification and claims as originally filed. Support for the recitation of "at least 70% identical to SEQ ID NO:1" and "at least 95% identical to SEQ ID NO:1" can be found in, *e.g.*, originally filed claim 1 and page 5 lines 28-30. Support for "a subsequence of at least 30 nucleotides of SEQ ID NO:1" is found on, *e.g.*, page 4 lines 18-22. The recitation of "a promoter operably linked to" a polypeptide is supported by, *e.g.*, originally filed claim 1. The elements of "tissue-specific promoter," "promoter preferentially directs transcription in guard cells," and "KAT1 promoter" are found in originally filed claims 2, 3, and 4. The recitation of "decreased turgor pressure in guard cells" or "decreasing turgor pressure in guard cells" is supported by originally filed claim 3. The means of generating a transgenic plant "through sexual cross" and by "using *Agrobacterium*" are found in originally filed claims 9 and 10, respectively. No new matter is added.

Applicants note that the newly added claims are directed to the same invention as the originally filed claims. Claims 44-49 are directed to isolated nucleic acids and correspond to claims 11-19. Claims 50-55 are directed to transgenic plants and correspond to claims 20-27. Claims 56-61 are directed to methods of producing transgenic plants and correspond to claims 1-10. In particular, the scope of claim 56 corresponds to that of claim 3 as originally filed. As such, Applicants submit that the new claims are drawn to the same invention as the original claims and should be considered on the merits.

The present amendment to the specification merely corrects some typographic errors and introduces no new matter.

### **III. Claims Rejections**

#### **A. 35 USC §112 Second Paragraph**

In the Office Action mailed October 4, 2002, the Examiner rejected claims 1, 5-8, 11-16, 20, and 24-27 under 35 USC §112 second paragraph for alleged indefiniteness. Specifically, the rejections were based on the use of phrases "ABH1 polynucleotide sequence," "modulates," "at least about," "and" following "plant," as well as some typographic errors. Since the new claims do not recite the terms or contain these errors, the rejections are moot. Applicants thus respectfully request the withdrawal of the rejections under 35 USC §112 second paragraph.

#### **B. 35 USC §101 and 35 USC §112 First Paragraph**

Claims 1-27 were rejected under 35 USC §101 for alleged lack of utility. In light of the cancellation of claims 1-27, Applicants address the rejections to the extent that they may be applicable to the new claims 44-61.

New claims 44-49 are directed to an isolated nucleic acid comprising an expression cassette, which comprises a promoter operably linked to a polynucleotide that is at least about 70% identical to SEQ ID NO:1 or is a subsequence of at least 30 nucleotides of SEQ ID NO:1, the nucleic acid leads to decreased turgor pressure when expressed in guard cells. New claims 50-55 are directed to a transgenic plant comprising a nucleic acid, which comprises a promoter operably linked to a polynucleotide that is at least about 70% identical to SEQ ID NO:1 or is a subsequence of at least 30 nucleotides of SEQ ID NO:1, and having decreased turgor pressure in guard cells. New claims 56-61 are directed to a method for producing a transgenic plant, comprising the step of introducing into the plant an isolated nucleic acid, which comprises an expression cassette comprising a tissue-specific promoter operably linked to a polynucleotide that is at least 70% identical to SEQ ID NO:1 or is a subsequence of at least 30 nucleotides of SEQ ID NO:1, wherein the tissue-specific promoter preferentially directs transcription of the polynucleotide in guard cells and thereby decreases turgor pressure in guard cells in the plant.

The specification provides description of the utility of the claimed nucleic acid, the transgenic plant, and the method for producing the plant. It is known that ABA mediates turgor pressure in guard cells and thus stomatal closure in a plant in response to drought (page 1 line 24 and page 4 lines 20-22). The present application also provides experimental evidence that loss of ABH1 function leads to heightened sensitivity to ABA in a plant (*see e.g.*, page 21 lines 31-32). Most significantly, under drought conditions, plants with diminished ABH1 activity remained green and turgid while plants with normal level of ABH1 protein showed leaf chlorosis and wilting (page 23 lines 4-16). The reduction of ABH1 protein activity in a plant, as demonstrated by the present invention, can thus enhance the plant's drought tolerance. Applicants assert that this is a well established and specific utility. On the other hand, the Examiner has not identified any particular reason why the asserted utility would not be considered creditable by one of ordinary skill in the art in light of the present disclosure.

The Examiner further rejected the claims under 35 USC §112 first paragraph, stating that since the claimed invention lacks utility, one of skill in the art would not know how to use the invention. As explained above, the present invention has a well established, specific, and credible utility and thus, one skilled in the art will know how to use the invention. The enablement of the claimed invention is addressed more fully below.

Applicants respectfully request the withdrawal of the rejections under 35 USC §101 and §112 second paragraph for alleged lack of utility.

C. 35 USC §112 First Paragraph

*Written Description*

Claims 1-5, 7, 9-12, 14, 16-24, and 26 were rejected under 35 USC §112 first paragraph for alleged failure to satisfy the written description requirement. In light of the cancellation of claims 1-27, Applicants address the rejections to the extent that they may be applicable to the new claims.

Claims 1-27 are directed to ABH1 polynucleotide sequences with at least 70% identity to SEQ ID NO:1 and ABH1 polypeptide sequences with at least 70% identity to SEQ ID NO:2. The Examiner asserted that, without disclosing the functional structure of the ABH1 polypeptide, the specification does not properly describe the invention in the scope as claimed.

To satisfy the requirement of written description, an application must describe the claimed invention in sufficient detail such that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. MPEP §2163 Sec. I.

New claims 44-61 relate to an isolated nucleic acid comprising an expression cassette, which comprises a polynucleotide that is further described as at least 70% identical to SEQ ID NO:1 or an at least 30-nucleotide fragment of SEQ ID NO:1. Decreased turgor pressure will result when the nucleic acid is expressed in guard cells. The new claims fully comply with the requirements for written description of a chemical genus as set forth in *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398 (Fed. Cir. 1993). The Federal Circuit stated in *Lilly*, "[a] description of a genus of cDNAs may be achieved by means of ... a recitation of structural features common to the members of the genus...." 43 USPQ2d at 1406. The Federal Circuit further stated that an adequate written description "requires a precise definition, such as by structure, formula, chemical name, or physical properties." *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). New claims 44-51 set forth the structural feature of the claimed genus of nucleic acids: they all comprise an expression cassette, which includes a promoter operably linked to a polynucleotide sequence that has a defined percentage identity to SEQ ID NO:1 or is a fragment of SEQ ID NO:1 in a length of at least 30 nucleotides. Therefore, the nucleic acid molecules of the claims are defined via shared structural features, and the written description requirement under *Lilly* is satisfied.

Furthermore, new claims 44-61 also set forth the functional feature of the genus of nucleic acids: the ability to decrease turgor pressure in guard cells when

expressed. With both structural and functional features of the claimed nucleic acids precisely defined, Applicants submit that the written description requirement under prevailing case law is satisfied and thus respectfully request that the written description rejections be properly withdrawn.

*Enablement*

Claims 1-27 were rejected under 35 USC §112 first paragraph for alleged failure to meet the enablement requirement. In light of the cancellation of claims 1-27, Applicants address the rejections to the extent that they may be applicable to the new claims.

The recitation of percentage identity to SEQ ID NO:1 or 2 in claims 1-27 was again used as the basis for the enablement rejections. The Examiner stated that one skilled in the art would not know how to practice the invention as claimed when the functional structure of ABH1 protein is not disclosed.

To satisfy the enablement requirement, an application must contain sufficient information regarding the subject matter of the claims so as to enable one skilled in the art to make and use the claimed invention. MPEP §2164.01. The test for enablement is set forth in *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988), and requires consideration of multiple factors including: the breadth of the claims; the nature of the invention; the state of the prior art; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In the present case, the new claims are directed to a nucleic acid comprising an expression cassette, which comprises a promoter operably linked to a polynucleotide sequence with a structure definitively referred to SEQ ID NO:1 and a readily testable functional feature. The claim scope is neither overly broad nor vague. The specification has set forth detailed description of experimental procedures for testing

the change in turgor pressure by measuring stomatal closure in guard cells (*e.g.*, page 21 line 27 to page 23 line 16). These procedures rely on techniques well known to those skilled in the pertinent art. The specification also contains ample guidance to practice the invention, such as methods of isolating ABH1 polynucleotide sequences of the claimed nucleic acid genus (*see, e.g.*, page 16 line 12 to page 17 line 18), preparation of recombinant vectors (*see, e.g.*, page 17 line 20 to page 19 line 3), productions of transgenic plants (*see, e.g.*, page 19 line 5 to page 20 line 24), and assays for testing heightened ABA sensitivity (*see, e.g.*, Examples on page 21 line 27 to page 23 line 16). The level of technical sophistication is high in the art of molecular biology, and the results are relatively predictable. Although some experimentation may be necessary to identify the ABH1 polynucleotide sequences useful for practicing the invention, such experimentation utilizes well-established techniques and is routinely conducted in the art and therefore does not constitute undue experimentation. MPEP §2164.01.

In summary, Applicants believe that the disclosure by the present application is sufficiently enabling for a person with ordinary skill in the art to practice the invention and that no undue experimentation is required. The claim rejections for inadequate enablement should thus be properly withdrawn.

D. 35 USC §102

Claims 11 and 14-18 were rejected 35 USC §102(b) for allegedly being anticipated by NCBI Accession Number 4558656 (Lin et al.). In light of the cancellation of claims 1-27, Applicants address the rejections to the extent that they may be applicable to the new claims.

In order to anticipate a claim, a reference must teach or suggest all elements of the claim. MPEP §2131. Lin et al. disclose a DNA sequence from *Arabidopsis* that encodes for a polypeptide comprising the amino acid sequence of SEQ ID NO:2. New claims 44-49 are drawn to a nucleic acid comprising an expression cassette, which comprises a promoter operably linked to a polynucleotide with sequence

homology to SEQ ID NO:1. Decreased turgor pressure results when the claimed nucleic acid is expressed in a guard cell.

The Lin reference refers to a number of open reading frames apparently from genomic DNA isolated from *Arabidopsis*. The Examiner does not identify the particular open reading frame in the Lin reference that allegedly corresponds to the claimed nucleic acids. Applicants note, however, that protein ID AAD22677.1 appears to share some sequence identity with SEQ ID NO: 2. Lin identifies this protein as being an "unknown protein" and does not reveal any information regarding its function.

Claims 44-49 are directed to expression cassettes comprising the nucleic acids of the invention. Lin fails to describe the construction of expression cassettes using the nucleic acids disclosed there. Thus, the Lin reference cannot anticipate the nucleic acid claims of the instant application.

In addition, Lin et al. do not teach the function of the protein the amino acid sequence of which is set forth in SEQ ID NO:2, one skilled in the art would not be motivated to use the claimed nucleic acids to enhance ABA sensitivity in plants or to generate a transgenic plants with higher drought tolerance. The claims of the present invention are therefore not obvious in light of Lin et al.


Applicants respectfully request the withdrawal of the rejections under 35 USC §102.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE SPECIFICATION:**

In the second paragraph under the title "DETAILED DESCRIPTION OF THE INVENTION":

-- Results presented here indicate that ABH1 is a modulator of ABA signal transduction. ABH1 modulates the ABA sensitivity of seed germination, of ABA-induced stomatal closing, of ABA-induced guard cell  $[Ca^{2+}]_{cyt}$  elevations and whole plant transpirational water loss during drought. Growth analyses with other plant hormones showed an ABA specificity of *abh1*. The *abh1* mutant is the first plant mutant shown to enhance signal-induced  $[Ca^{2+}]_{cyt}$  elevations [evations]. Calcium imaging data demonstrate that ABH1 modulates early ABA signal transduction events. Human and yeast nuclear CBCs function in pre-mRNA [pre-mRNA] splicing (E. Izaurralde *et al.*, *Cell*, 78:657 (1994); J. D. Lewis *et al.*, *Nucleic Acids Res.*, 24:3332 (1996)) and affect the expression of a specific subset of genes in yeast (P. Fortes *et al.*, *Mol. Cell. Biol.*, 19:6543 (1999)). The nuclear CBC further regulates mRNA 3' end formation and RNA export in humans, and translation in yeast (E. Izaurralde *et al.*, *Nature*, 376:709 (1995); P. Fortes *et al.*, *Mol. Cell.*, 6:191 (2000)). Interestingly, the human nuclear CBC has recently been suggested to function as a target in growth factor and stress-activated signaling, regulating the expression of specific genes (K. F. Wilson *et al.*, *J. Biol. Chem.*, 274:4 166 (1999)). The discovery of *abh1* provides genetic evidence that a nuclear cap binding protein regulates ABA signaling in plants. Based on the mRNA cap binding activity ABH1 may regulate mRNA processing of early ABA signal transduction genes. Furthermore ABH1 modulates the strength of plant responses to ABA and therefore could provide a new control mechanism for manipulating the ABA responsiveness of crop plants during stress.--